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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61N 5/10, A61M 25/10

A1

(11) International Publication Number: WO 99/40971

(43) International Publication Date: 19 August 1999 (19.08.99)

(21) International Application Number: PCT/US99/03327

(22) International Filing Date: 17 February 1999 (17.02.99)

(30) Priority Data:
09/024,327 17 February 1998 (17.02.98) US

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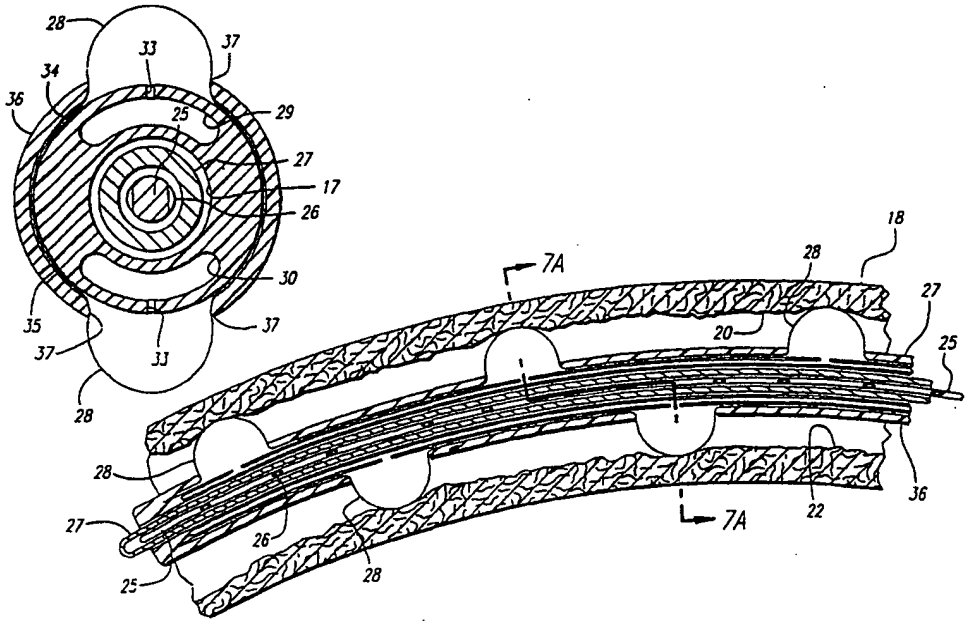
(81) Designated States: JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: RADIATION DELIVERY CATHETER WITH BLOOD PERFUSION CAPABILITY



(57) Abstract

The invention is directed to a radiation delivery catheter with blood perfusion capability suitable for maintaining patency of a body lumen for a period of time sufficient to prevent delivery of a radiation source to the body lumen. The catheter utilizes an inflatable region which maintains and centers the catheter in the body lumen while allowing blood to perfuse therethrough. The inflatable region can be made up of discrete, segmented balloon elements which are oriented to create a passageway for blood to flow when the balloon elements are inflated. Additionally, the inflatable region can be made from a plurality of nodular balloon elements which expand from the elongated catheter body to contact the wall of the body lumen to permit blood flow through the inflatable region while radiation therapy is being provided.

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RADIATION DELIVERY CATHETER WITH BLOOD PERFUSION CAPABILITY

BACKGROUND OF THE INVENTION

This invention generally relates to intravascular catheters and particularly to an intravascular catheter assembly for delivering radiation treatment to a body lumen while providing blood perfusion through the body lumen past and around the catheter.

In percutaneous transluminal coronary angioplasty (PTCA) procedures, a guiding catheter having a preshaped distal tip is percutaneously introduced into the cardiovascular system of a patient through the brachial or femoral artery and is advanced therein until the preshaped distal tip is disposed within the aorta adjacent to the ostium of the desired coronary artery. The guiding catheter is then twisted and torqued from its proximal end to turn its distal tip so that it can be guided into the coronary ostium. In an over-the-wire dilatation catheter system, a guide wire and a dilatation catheter having an inflatable balloon on the distal end thereof are introduced into, and advanced through, the proximal end of the guiding catheter to the distal tip of the guiding catheter seated within the coronary ostium. The distal tip of the guide wire is usually manually shaped (i.e. curved) by the physician or one of the attendants before it and the dilatation catheter are introduced into the guiding catheter. The guide wire is usually first advanced out of the distal end of the guiding catheter and is maneuvered into the patient's coronary vasculature containing the stenosis to be dilated, and is then advanced beyond the stenosis. Thereafter, the dilatation catheter is advanced over the guide wire until the dilatation balloon is positioned across the stenosis. Once the dilatation catheter is in positioned, the balloon of the catheter is filled with radiopaque liquid at relatively high pressures (e.g., generally about 4-12 atmospheres) to inflate it to a predetermined size (preferably the same as the inner diameter of the artery at that particular location) in order to radially compress the atherosclerotic plaque of the stenosis against the inside of the wall of the artery, thereby increasing the diameter of the occluded artery. The balloon can then be deflated so that the catheter can be removed and blood flow resumed through the dilated artery.

One common problem that sometimes occurs after an angioplasty procedure has been performed is the restenosis at, or near, the original site of the stenosis. When restenosis occurs, a second angioplasty procedure or even bypass surgery may be required,

depending upon the degree of restenosis. In order to reduce the likelihood of the development of restenosis and thereby prevent the need to perform bypass surgery or subsequent angioplasty procedures, various devices and procedures have been developed for preventing restenosis after arterial intervention. For example, an expandable cage (commonly termed "stent") designed for long term implantation with the body lumen has been utilized to help prevent the occurrence of restenosis.

More recent devices and procedures for preventing restenosis after arterial intervention employ the use of a radiation source to reduce the proliferation of smooth muscle cells which are believed to be the primary cause of restenosis. Balloon catheters have been used to deliver and maintain the radiation source in the area where arterial intervention has taken place, exposing the area to a sufficient radiation dose to inhibit cell growth. Two devices and methods are described in International Publication No. WO 93/04735 (Hess) and WO 95/19807 (Weinberger). Other devices and methods which utilize radiation treatment delivered by an intravascular catheter are disclosed in commonly-owned and assigned co-pending application U.S. Serial No. 08/654,698, filed May 29, 1996, entitled Radiation-Emitting Flow-Through Temporary Stent and co-pending application Serial No. 08/705,945, filed August 29, 1996, entitled Radiation Dose Delivery Catheter with Reinforcing Mandrel, which are incorporated herein by reference. Another medical device for the treatment of a body vessel by radiation is disclosed in European Patent App. 0 688 580 A1 (Schneider).

One problem common to many of the balloon catheters which provide radiation treatment to a particular part of a patient's vascular system is that it is sometimes preferable to treat the target area with a lower radiation dosage over a longer period of time rather than a higher dosage of radiation over a shorter period of time. If conventional balloon catheters are utilized to hold open the area of an artery where restenosis is likely to occur to allow delivery of a radiation source, then the inflated balloon will inhibit or restrict the flow of blood through the artery, which can pose serious risk of damage to tissue downstream from the occluded portion of the artery since the tissue will express a deprivation of oxygenated blood. As a result, the time in which the balloon can remain expanded within the artery would be diminished, effecting the time period in which the radiation dosage can be maintained in the area of the artery where restenosis may occur. Thus, a higher dosage of radiation may have

to be administered over a shorter period of time due to the occlusion of the vessel caused by the inflated balloon catheter, which again, may not be as advantageous as providing a lower dosage over a longer period of time.

What has been needed and heretofore generally unavailable in catheters which provide treatment of the body vessel with a radiation source is an intravascular catheter assembly which allows delivery of a radiation source to the area where restenosis may occur for a period of time sufficient to selectively destroy the cells and prevent development of restenosis while allowing blood to perfuse pass the occluded region during the radiation procedure. Such an intravascular catheter would have to be relatively easy and inexpensive to manufacture, have an expandable region that is strong and reliable under pressure, and capable of being formed in a variety of shapes to allow flexibility in the amount and pattern of expansion and deformation of the expandable region. The present invention satisfies these and other needs as will be described hereinafter.

SUMMARY OF THE INVENTION

The present invention is directed to an intravascular catheter with an expandable region located at the distal end of the catheter body which can hold open a body lumen for a sufficient period of time to permit delivery of a radiation source to the body lumen while permitting perfusion of blood through the vessel.

The intravascular catheter in accordance with the present invention includes an elongated catheter body having proximal and distal ends, a guide wire lumen extending at least partly through the elongated catheter body and an inflatable region located near the distal end of the elongated catheter body which include communication with an inflation lumen which extends from the proximal end of the catheter body.

The inflation region is configured to be flexible so that it can be expanded on a curved portion of a body lumen, such as a coronary artery. It is also configured to center a radiation source wire within the body lumen, even if the inflatable region is positioned on a curved section of the body lumen. The inflation region performs all of these features while

still allowing blood to flow past it to supply oxygenated blood to tissue downstream from the catheter when the inflated region is in its expanded position.

The intravascular catheter of the present invention allows for an over-the-wire delivery for the advancement thereof of the elongated catheter body to a location within a body lumen where the radiation dose is to be administered. The guide wire lumen is used both for advancing the elongated catheter body to the target area and for advancing a radiation source wire to target area as well. After the catheter is in place with the inflatable region inflated to its expanded position with the artery, the guide wire is removed from the guide wire lumen to allow the radiation source wire to be advanced to the target area. The exchange may be done by first placing a protective sheath into the guide wire lumen by utilizing a support mandrel which advances the sheath into its proper position within the guide wire lumen. Thereafter the support mandrel can be removed to allow the radiation source wire to be advanced from the radiation source storage facility where it could be advanced through the protective sheath to the targeted area. Once the radiation source wire has been positioned to provide the necessary radiation dosage, the inflatable region can be deflated to its original unexpanded state and the catheter and radiation source wire can then be removed from the patient's vasculature.

In one particular embodiment of the present invention, the inflatable region is made from the plurality of discrete segmented balloon elements which are deposed along the distal end of the elongated catheter body. Each individual balloon segment has a pair of side walls opposite each other which produced a very low profile balloon segment which has a relatively small contact region which contacts the wall of the artery upon inflation. Each individual balloon segment is oriented approximately 90 degrees from each adjacent balloon segment to increase the area between the walls of the balloon segments to create an expanded passage through which blood passes through when the balloon segments are inflated. This particular configuration of individual balloon segments creates sufficient support within the artery to maintain the catheter in place and to center the radiation source wire within the body lumen, while still permitting a sufficient passage to allow the blood to flow over and past the individual balloon segments during inflation to prevent deprivation of oxygenated blood to tissue downstream of the inflatable region.

In another particular embodiment of the present invention, the inflatable region is made from a plurality of individual nodular elements which protrude from the surface of the elongated catheter body when inflated. These nodular elements, when expanded, have sufficient contact area to maintain the catheter in the target area in the artery and also allow for the centering of the radiation source wire within the artery. Since these plurality of nodular elements are spaced apart from one another, they provide a sufficient passageway for blood to flow past each individual nodular element, even when expanded, to allow blood perfusion past the catheter during the radiation treatment. These nodular elements can be made from elastic (distensible) materials which allows the catheter to maintain a extremely thin profile when the nodular elements are in their unexpanded condition but will sufficiently inflate once in their expanded position to maintain and hold the catheter in the target area. As described below, there are several ways in which to form these expandable nodular elements on the elongated catheter body to achieve a successful intravascular catheter with blood perfusion capabilities.

These and other advantages of the invention will become more apparent from the foregoing detailed description thereof when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a perspective view depicting the inflatable region of an intravascular catheter embodying features of the present invention.

FIG. 2 is a cross-sectional end view of the catheter of FIG. 1 depicting the inflatable region in its expanded condition within an artery.

FIG. 3 is a cross-sectional view of the inflatable region of the catheter of FIG. 1, in which the inflatable region is expanded within a curved section of artery, thereby centering the radiation source wire within the artery.

FIG. 4 is a perspective view of one embodiment of an inflatable region of an intravascular catheter embodying features of the present invention.

FIG. 5 is a cross-sectional view of the inflatable region of FIG. 4, in its unexpanded condition.

FIG. 6 is a cross-sectional view of the inflatable region of FIG. 4, in its expanded condition.

FIG. 7 is a cross-sectional view of the inflatable region of FIG. 4, in which the inflatable region is expanded within a curved section of artery, thereby centering the radiation source wire within the artery.

FIG. 7A is a cross-sectional view of the inflatable region of FIG. 4, taken along lines 7A-7A, showing the inflatable region fully expanded within the artery, thereby centering the radiation source wire.

FIG. 8 is a perspective view of another embodiment of an inflatable region of an intravascular catheter embodying features of the present invention.

FIG. 9 is a cross-sectional view of the inflatable region of FIG. 8, in its unexpanded condition.

FIG. 10 is a cross-sectional view of the inflatable region of FIG. 8, in its expanded condition.

FIG. 11 is a cross-sectional view of the inflatable region of FIG. 8, showing the inflatable region in its expanded condition within a curve section of artery, thereby centering the radiation source wire within the artery.

FIG. 11A is a cross-sectional view of the inflatable region of FIG. 11, taken along lines 11A-11A, showing the inflatable region as it is expanded within a curved section of artery, thereby centering the radiation source wire within the artery.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides an intravascular catheter for delivery and maintaining a low dose radiation source to a patient's body lumen, such as a coronary artery or other vessel, for an extended period of time. The catheter permits perfusion of blood during the radiation therapy and will center the radiation source so that equal amounts of radiation will be applied to the artery. While the invention is described in detail as applied to the coronary arteries, those skilled in the art will appreciate that it can also be used in other body lumens as well, such as peripheral arteries and veins. Where different embodiments have like elements, like reference numbers have been used.

FIGS. 1-3 illustrate an intravascular catheter assembly 10 embodying features of the present invention. Catheter assembly 10 generally includes an elongated catheter body 11 with an inflatable region 12 on the distal portion thereof and an adapter 13 on a proximal end thereof. An inner tubular member 14 extends coaxially with an outer tubular member 15 and defines an annular inflation lumen 16 which extends from the proximal end of the elongated catheter body 11 to the inflatable region 12 and connects in fluid communication the interior of the inflatable region 12 with a source of inflation fluid at the proximal end of the catheter assembly 10. The distal end of the inner and outer tubular members 14 and 15 are joined together by suitable means such as adhesive or heat bonding to seal the inflation lumen 16.

The elongated catheter body 11 includes a guide wire lumen 17 positioned in the distal portion of the elongated catheter body which extends from the proximal to distal end of the elongated catheter body 11. A guide wire (not shown) would be slidably disposed within the guide wire lumen 17 to facilitate the advancement and replacement of the catheter 10 within the artery 18. As can be seen in FIG. 1, the inflatable region 12 is made up of a plurality of discrete balloon elements 19 which are attached to the elongated catheter body 11

and are in fluid communication with the inflation lumen 16 in order to inflate and deflate the balloon elements simultaneously.

FIG. 2 shows a cross-sectional view of the discrete balloon elements 19 in an inflated condition positioned within the artery 18. As is shown in FIGS. 2 and 3, each balloon element contacts the wall 20 of the artery only along a contact surface 21 of the balloon element. As a result, a passageway 22 is created between the wall of the artery and the side walls 23 and 24 of each balloon element to create a fluid conduit which allows blood to flow past each balloon element upon inflation. The radiation source wire 25 which is advanced within the guide wire lumen 17 remains centered within the artery 18. Thus, during the administration of the radioactive dosage, blood perfusion will still be permitted past the distal end of the catheter assembly allowing the radiation treatment to be delivered over a much more extended period of time.

As can be seen in FIGS. 1 and 2, each individual discrete balloon element 19 is oriented approximately 90 degrees from each adjacent inflation element to provide a sufficient passageway 22 which allows blood perfusion during the radiation treatment. It should be appreciated that each balloon element 19 can be oriented from each other at different angulations to perform substantially the same function of creating a sufficient flow passage to permit blood perfusion during the radiation treatment. In the embodiment shown in FIG. 1, five individual balloon elements are shown; however, it should be appreciated that more or less balloon elements could be utilized in accordance with the present invention. Additionally, while each individual balloon element is shown directly contacting one another, it is also possible to place segments of non-inflatable segments between each balloon element to achieve a similar passageway for blood perfusion past the inflatable region 12.

Each balloon element 19 has a low profile configuration to form a sufficiently large passageway to allow blood to perfuse when the balloon elements are in the expanded condition. In the embodiment shown in FIGS. 1-3, the side walls 23 and 24 of each balloon segment are shaped in substantially square configurations to achieve proper centering of the radiation source wire within the artery. It should be appreciated that the side walls 23 and 24 can also be configured in other shapes, for example rectangularly, to provide proper centering of the radiation source wire within the artery. The low profile of each balloon element creates

a contact surface 21 which is sufficiently large to make contact with the wall of the artery upon expansion to center and maintain the catheter within the artery, but is still small enough to create a sufficiently large passageway for blood perfusion. It should also be appreciated that the length and width of these contact surfaces may be varied as well. However, the profile (i.e., the distance between the two side walls) should be sufficiently large enough to support and maintain the catheter within the artery upon expansion, but small enough to create a sufficient passage for blood flow. Since each individual balloon element is staggered 90 degrees from each other, a sufficiently large passageway should be formed.

As can be seen in FIGS. 2 and 3, once the intravascular catheter 10 has been properly positioned within the artery 18, the guide wire (not shown) can be removed from the guide wire lumen 17 and a radiation source wire 25 can be inserted into the guide wire lumen 17 for a period of time sufficient to provide the radiation dosage to the body lumen. Preferably, the radiation source wire 25 is hollow at its distal end and contains a radiation dose in the form of a radiation source 26, such as pellets, radiation gas, or radioactive liquid or paste. The radiation source wire 25 may have a radioactive source coated on its distal end. This radiation source wire 25 provides the proper doses of radiation to the areas of the artery 18 where arterial intervention has been performed, either by PTCA, atherectomy, stenting or other means to help inhibit the proliferation of neo-intima in this region. A protective sheath 27, which encases the radiation source wire 25, seals the radiation source from exposure to any body fluids, such as blood, and to provide a sterile barrier between the radiation source wire 25 (which can be reusable and non-sterile) in the patient's vascular system. It is preferable that radiation source wire 25 be stored and its deployment controlled by an afterloader (not shown) which is known in the art.

In practice, once the catheter assembly 10 has been placed within the vasculature of the patient, the guide wire can be removed from the guide wire lumen 17 to allow the protective sheath 27 to be loaded into the guide wire lumen utilizing a support mandrel (not shown). Once the protective sheath 27 has been properly placed within the guide wire lumen 17, the support mandrel can be removed from the proximal end of the catheter assembly. The radiation source wire 25 can then be advanced through the protective sheath 27 by the afterloader to the target area where the radiation therapy is to be provided. It is

noted that reference herein to the "target area" means that part of the body lumen that has received a PTCA, atherectomy, or similar procedure to reduce or remove a stenosis, which is subject to the development of restenosis caused, in part, by intimal hyperplasia or the proliferation of smooth muscle cells.

Once the required period of time for treatment has been completed, the inflatable region 12 can be deflated, allowing the entire catheter assembly and radiation source wire 25 to be removed from the body lumen. It should be appreciated that the proximal end of the protective sheath 27 can be connected to an afterloader where the radiation source wire may be stored during the initial set up procedure when the catheter assembly is positioned in the target area. Thereafter, the radiation source wire can be advanced from the afterloader through the protective sheath to the target area, preventing or reducing possible exposure of the radiation source to personnel performing the radiation procedure.

In another preferred embodiment of the invention, as shown in FIGS. 4-7A, the intravascular catheter utilizes an inflatable region 12 which is made up of a plurality of nodular elements 28, which when expanded, extend outwardly from the surface of the catheter body 11 to contact the wall 20 of the artery 18 during the radiation procedure. Referring specifically to FIGS. 7 and 7A, nodular elements 28 are shown as they contact the wall 20 of the artery upon inflation. Since the nodular elements are spread apart from one another and have a minimum contact area with the wall of the artery, passageway 22 is created to allow blood flow past the nodular elements when they are expanded. These individual nodular elements 28 provide an inflatable region 12 which maintains the catheter in the target area and centers the guide wire lumen 17, which in turn allows the radiation source wire 25 to be centered within the artery during radiation treatment.

Referring specifically to FIGS. 5 and 6, the particular construction of the inflatable region 12 of the catheter depicted in FIG. 4 is shown in greater detail. The elongated catheter body 11 includes a pair of inflation lumens 29 and 30 to inflate rows 31 and 32 of nodular elements 28, which are formed opposite to each other on the elongated catheter body 11. Each inflation lumen 29 and 30 has a plurality of openings 33 which extend through the outer surface 34 of the catheter body into the respective inflation lumens. A thin layer of elastic material 35 is disposed over the outer surface 34 of the elongated catheter body 11 to

"encapsulate" the distal end of the catheter. An outer sleeve 36 made from an in elastic material is placed over the thin layer of elastic material 35 at the distal end. This outer sleeve 36 has a plurality of openings 37 cut therein which are placed over the openings 33 formed on the elongated catheter body 11. When inflation fluid is pumped into the inflation lumens 29 and 30, as is shown in FIG. 6, the fluid causes the thin layer of elastic material 35 to expanded through the openings 37 in the outer sleeve 36, forming the individual nodular elements 28. As the fluid pressure from the inflation fluid increases, the size of each nodular elements increases accordingly until the nodular elements contact the wall of the artery to maintain and center the catheter in place. When the catheter is to be removed from the artery, the inflation fluid is purged from the inflation lumens, causing the thin layer of elastic material 35 to revert back to its initial unexpanded shape as shown in FIG. 5.

In usage, an intravascular catheter utilizing an inflation region 12, as the one shown in FIG. 4, would be positioned into the target area of the artery 18 by sliding the catheter assembly over a guide wire which is already positioned in the target area. The inflation region 12 can then be inflated to cause the nodular elements to extend outward from the surface of the elongated catheter body to contact and press against the wall of the artery. The guide wire can then be removed from the guide wire lumen 14 to allow the protective sheath 25 to be loaded into the guide wire lumen utilizing a support mandrel. Once the protective sheath 27 is in place, the support mandrel can be removed to allow the radiation source wire 25 to be advanced to the targeted area within the artery. Once the radiation procedure has been completed, the nodular elements can be deflated accordingly and the catheter, radiation source wire and protective sheath can then be removed from the patient's vasculature.

In another embodiment of the present invention, as shown in FIGS. 8-11A, the catheter includes an inflatable region 12 made from a plurality of nodular elements 38 which extend from the outer surface 39 of the elongated catheter body 11. In accordance with the nodular elements shown in the embodiment of FIGS. 4-7A, these nodular elements 38 are designed to be inflated within the target area of the artery to maintain the catheter in place and to center the radiation source wire during the procedure. As can be seen in FIGS. 9 and 10, each nodular element 38 is individually formed in an outer tubular member 40 which

comprises part of the elongated catheter body 11. An inner tubular member 41 which extends the length of the catheter assembly includes a guide wire lumen 17 formed therein. In this particular embodiment, the inflation lumen 16 is formed in the space between the outer tubular member 40 and inner tubular member 41. As with the embodiment shown in FIG 4-7A, these nodular balloon elements 38 are arranged in rows 42 and 43 along the outer tubular member 40.

FIG. 9 shows the nodular elements 38 as they would remain in the unexpanded position on the catheter. In this particular figure, the material making up each nodular element is folded along the outer surface 39 of the outer tubular member 40. In this manner, the overall catheter profile is reduced to allow the catheter to more easily navigate within the vasculature of the patient. Thereafter, inflation within the inflation lumen 16 causes the nodular elements 38 to extend outwardly to form the expanded shape depicted in FIG. 8. Again, the nodular balloon elements 38 are designed to extend outwardly to contact a portion of the wall 20 of the artery 18 to maintain the catheter in place and to center the guide wire lumen allowing the radiation source wire 25 to be centered within the artery during the procedure. The particular structure and use of the nodular elements 38 also creates a passageway 22 between the catheter and wall of the artery to permit blood flow during the radiation treatment. As such, the catheter can remain in the patient's vasculature for an extended period without the fear of possible tissue damage due to a lack of oxygenated blood to the tissue distal to the catheter.

While the inflatable regions shown in FIGS. 4 and 6 show a particular arrangement of the nodular balloon elements in a pair of rows which are disposed approximately 180 degrees from each other on the elongated balloon catheter, it is possible to stagger the spacing and orientation of the individual nodular balloon elements along the elongated catheter body to create an inflation region which is capable of centering the radiation source wire and will provide an adequate passageway for blood to flow. These nodular elements need not be arranged in just two rows, but rather can be arranged in more rows if desired. In fact, the nodular balloon elements need not be arranged in rows at all, but rather, can be strategically placed around the elongated catheter body as needed provided that the arrangement of nodular balloon elements cooperate to center the radiation source wire and

create a sufficiently large passageway for blood perfusion. Additionally, the particular size and shape of the nodular balloon elements can be varied to take on different shapes and sizes without departing from the spirit and scope of the present invention. In such a case, the shape and size of the nodular balloon element in the embodiment shown in FIG. 4 can be easily varied by changing the shape and/or size of the openings 37 which extend in the outer sleeve 36 of the catheter. Similarly, each nodular balloon element formed on the inflatable region of FIG. 8 could likewise be modified to different sizes and shapes to embody the features of the present invention.

Generally, the dimensions of the catheter assembly of the present invention are essentially the same dimensions of catheters used in angioplasty procedures. The overall length of the catheter may be about 100 to 175 cm, and preferably about 135 cm when a Seldinger approach through the femoral artery is employed. The diameter of the catheter body may range from about .030 to 0.100 inch. The inflatable region in its unexpanded condition has approximately the same diameter as the catheter body, but may be expanded to a maximum diameter of about one to about 5 mm for coronary arteries and substantially larger (e.g., 10 mm) for peripheral arteries. The diameter of the guide wire lumen should be sufficiently larger than the diameter of the guide wire and through the guide wire to allow the catheter to be easily advanced and removed from the guide wire. Additionally, the diameter of the guide wire should be sufficiently larger than the diameter of the radiation source wire and protective sleeve to allow these two devices to be easily advanced and removed from within the guide wire lumen.

In use, the inflatable region is held in its expanded condition for a time sufficient to allow the radiation dosage to effect those cells which would otherwise cause restenosis to develop. Preferably, a sufficient dose of radiation can be delivered from about one minute to about sixty minutes to prevent development of restenosis. In its expanded condition, the inflatable region presses against, or at least comes in close proximity to, the walls of the artery and in doing so centers the radiation source wire within the artery. Centering of this radiation source wire is important so that all portions of the artery receive as close to uniform and equal amounts of radiation as possible. Also, centering helps prevent radiation burns or hot spots from developing on portions of the target area.

The catheter assemblies of the invention as described herein are generally employed after an atherectomy, percutaneous transluminal coronary angioplasty procedure, or before or after stent implantation to allow the radiation dose to be administered to an area where restenosis might otherwise develop within a coronary artery. It should be recognized by those skilled in the art that the catheter of the present invention can be used within a patient's vasculature system after vascular procedures other than a PTCA, stent implantation or atherectomy have been performed.

The catheter assembly of the present invention may be formed from conventional materials of construction which are described in detail in prior art patents referenced herein. The materials forming the catheter body and protective sheath can be made out of relatively inelastic materials, such as polyethylene, polyvinyl chloride, polyesters and composite materials. The various components may be joined by suitable adhesives such as the acrylonitrile based adhesive sold as Loctite 405 or by other known methods. Heat shrinking or heat bonding may also be employed when appropriate. Additionally, the present invention can be made with a material to form the segmented balloon elements or nodular balloon elements that is elastic (distensible) since compression of plaque for this particular application is not required. An elastic material such as latex would be suitable for use. The radiation source wire can be made from materials such as stainless steel, titanium, nickel titanium (NiTi) and platinum nickel alloys, or any NiTi alloys, or any polymers and composites. Variations can be made in the composition of the materials to vary properties.

As described herein, the catheter assembly will allow delivery of radiation into the body lumen, such as a coronary artery, and is configured to provide the dosage over longer periods of time if necessary, due to the catheter's ability to allow blood to perfuse past the inflatable region during treatment.

The radiation delivered to a coronary artery should be in the range from about 20 to 3,000 rads in preferably not less than thirty seconds. The radiation dose can be delivered in less than thirty seconds, however, it is preferable that a longer time frame be used so that a more controlled, accurate dose can be administered in the target area.

It is contemplated that different radiation sources could be used, and the preferred radiation sources include iridium^{192} as a gamma emitter, and phosphorus^{32} as a beta

emitter. Further, it is contemplated that the radiation sources may provide beta particles or gamma rays to affect the target cells. However, alpha emitting radiation sources also can be used even though such radiation does not travel very far in human tissue. The use of beta and gamma emitting radiation sources is well known for treating and killing cancerous cells.

Other modifications can be made to the present invention without departing from the spirit and scope thereof. The specific dimensions, doses, times and materials of constructions are provided as examples and substitutes are readily contemplated which do not depart from the invention.

WHAT IS CLAIMED IS:

1. An intravascular catheter for maintaining the patency of a body lumen for a period of time sufficient to permit delivery of a radiation dose to the body lumen while permitting blood perfusion, comprising:

an elongated catheter body having a proximal end and a distal end;

an inflation lumen extending within the elongated catheter body to a location within a distal portion of the elongated body;

an inflatable region located near the distal end of the elongated catheter body in fluid communication with the inflation lumen, the inflatable region being expandable to contact a portion of the body lumen while permitting perfusion of blood past and over the inflatable region;

a guide wire lumen extending through at least a portion of the elongated catheter body for receiving a guide wire; and

a protective sheath adapted to encase a radiation source wire, the protective sheath and radiation source wire being insertable within the guide wire lumen to provide a radiation source to the body lumen.

2. The catheter of claim 1, wherein the inflatable region is made from a plurality of discreet balloon elements extending axially along the elongated catheter body, each balloon element having a first sidewall opposite a second sidewall with a contact surface connecting the first and second sidewalls together.

3. The catheter as defined in claim 2, wherein each balloon element has a first sidewall and a second sidewall each having a substantially square configuration.

4. The catheter as defined in claim 2, wherein each balloon element has a first sidewall and a second sidewall each having a substantially rectangular configuration.

5. The catheter as defined in claim 2, wherein each balloon element is angularly disposed approximately 90 degrees from an adjacent balloon element.

6. The catheter as defined in claim 2, wherein each balloon element is made from a distensible material.

7. The catheter as defined in claim 2, wherein the first and second sidewalls of each balloon element are substantially parallel to one another.

8. The catheter as defined in claim 7, wherein each balloon element is angularly disposed approximately 90 degrees from an adjacent balloon element.

9. The catheter as defined in claim 2, wherein the distance between the first and second sidewalls of each balloon element is substantially the same as an outer diameter of the elongated catheter body.

10. An intravascular catheter for maintaining the patency of a body lumen for a period of time sufficient to permit delivery of a radiation dose to the body lumen while permitting blood perfusion, comprising:

an elongated catheter body having a proximal end and a distal end;

an inflation lumen extending within the elongated catheter body to a location on a distal portion of the elongated body;

a plurality of nodular balloon elements forming an inflatable region located near the distal end of the elongated catheter body in fluid communication with the

inflation lumen, each nodular balloon element being expandable to contact a portion of the body lumen while permitting perfusion of blood past and over the inflatable region; and

a guide wire lumen extending through at least a portion of the elongated catheter body for receiving a guide wire and a radiation source wire to provide a radiation source to the body lumen.

11. The catheter as defined in claim 10, further including a protective sheath adapted to encase the radiation source wire to protect the radiation source wire from any bodily fluids in the body lumen, the protective sheath being insertable within the elongated catheter body.

12. The catheter as defined in claim 10, wherein a plurality of nodular balloon elements are disposed on an outer surface of the catheter body in a pair of rows, each row of nodular balloon elements being spaced apart from each other.

13. The catheter as defined in claim 10, wherein each nodular balloon element is expandable from an unexpanded condition in which each nodular balloon element is folded against the outer surface of the elongated catheter body.

14. The catheter as defined in claim 10, wherein each nodular balloon element is formed in a unitary piece of tubing.

15. An intravascular catheter for maintaining the patency of a body lumen for a period of time sufficient to permit delivery of a radiation dose to the body lumen while permitting blood perfusion, comprising:

an elongated catheter body having a proximal end and a distal end;

an inflation lumen extending within the elongated catheter body to a location on a distal portion of the elongated body;

a plurality of openings extending through the elongated catheter body into the inflation lumen;

a thin layer of elastic material disposed of the surface of the elongated catheter body near its distal end and over the plurality of openings;

an outer sleeve made from an inelastic material disposed over the layer of elastic material, the sleeve having a plurality of openings extending therethrough which are positioned adjacent the openings formed on the elongated catheter body, wherein inflating the inflation lumen with inflation fluid causes the elastic material to expand through the openings in the outer sleeve to form a plurality of nodular balloon elements, each nodular balloon element being expandable to contact a portion of the body lumen while permitting perfusion of blood through the inflatable region; and

a guide wire lumen extending through the elongated catheter body from the proximal end to the distal end for receiving a guide wire and a radiation source wire to provide a radiation source to the body lumen.

16. The catheter as defined in claim 15, further including a protective sheath adapted to encase the radiation source wire to protect the radiation source wire from any bodily fluids in the body lumen, the protective sheath being insertable within the body lumen.

17. The catheter as defined in claim 15, wherein the plurality of nodular balloon elements are disposed in a pair rows, each row of nodular balloon elements being disposed approximately 180 degrees from each other.

18. The catheter as defined in claim 15, wherein the shape and size of the openings in the outer tubular member defines the shape and size of each nodular balloon element.

19. The catheter as defined in claim 15, wherein the thin layer of elastic material which forms the nodular balloon elements is made from an elastic material.

20. A method for maintaining the patency of a body lumen for a period of time sufficient to permit delivery of a radiation dose to the body lumen while permitting blood perfusion, comprising the steps of:

a) providing a catheter having:

an elongated catheter body having a proximal end and a distal end;

an inflation lumen extending within the elongated catheter body to a location on a distal portion of the elongated body;

an inflatable region located near the distal end of the elongated catheter body in fluid communication with the inflation lumen, the inflatable region being expandable to contact a portion of the body lumen while permitting perfusion of blood through the inflatable region;

a guide wire lumen extending through at least a portion of the elongated catheter body for receiving a guide wire; and

a protective sheath adapted to encase a radiation source wire, the protective sheath and radiation source wire being insertable within the guide wire lumen to provide a radiation source to the body lumen;

b) positioning a guide wire in the body lumen;

c) advancing the catheter over the guide wire;

d) advancing the elongated catheter body over the guide wire until the inflatable region is in proper position in the body lumen;

e) inflating the inflatable region to contact the body lumen to center the guide wire lumen within the body lumen;

f) perfusing blood flow through and around the inflatable region;

g) removing the guide wire from the guide wire lumen;

h) inserting the protective sheath into the guide wire lumen;

i) inserting a radiation source wire into the protective sheath and advancing the protective sheath and radiation source wire to the desired area in the body lumen and administering a radiation dose;

j) deflating the inflatable region; and

k) withdrawing the catheter and the protective sheath and radiation source wire from the body lumen.

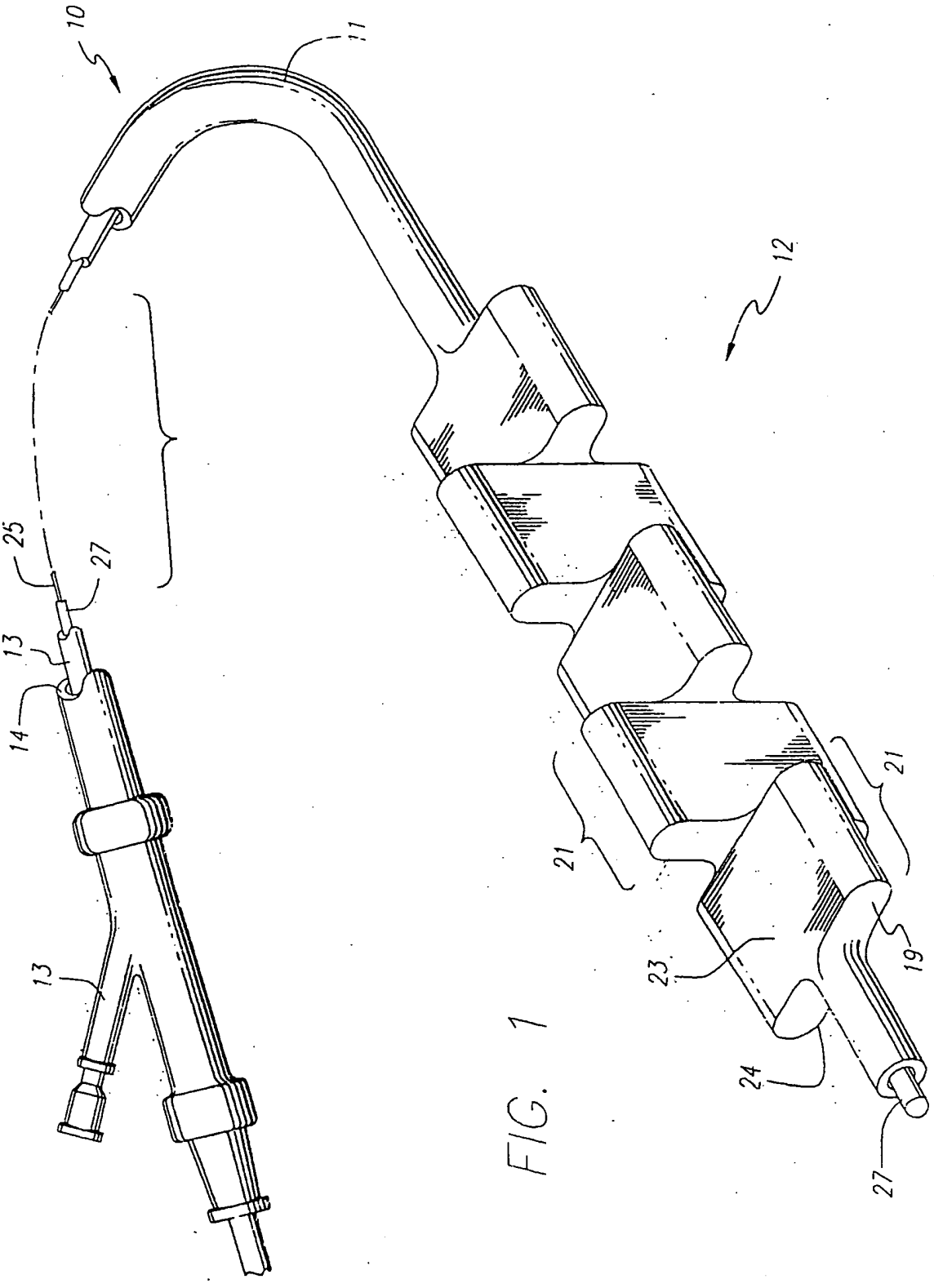

FIG. 1

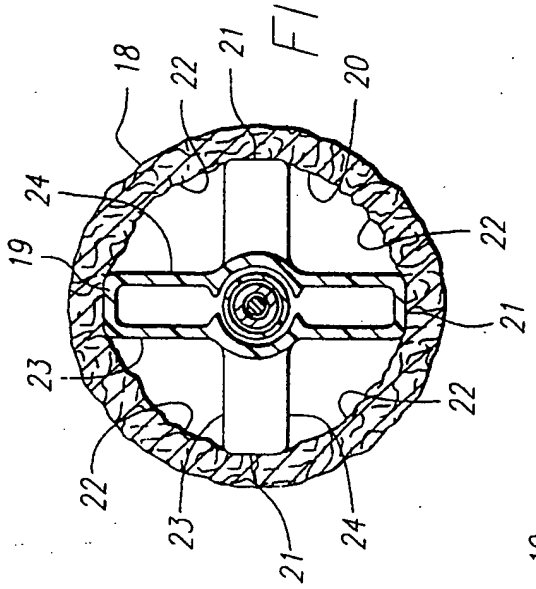
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FIG. 2

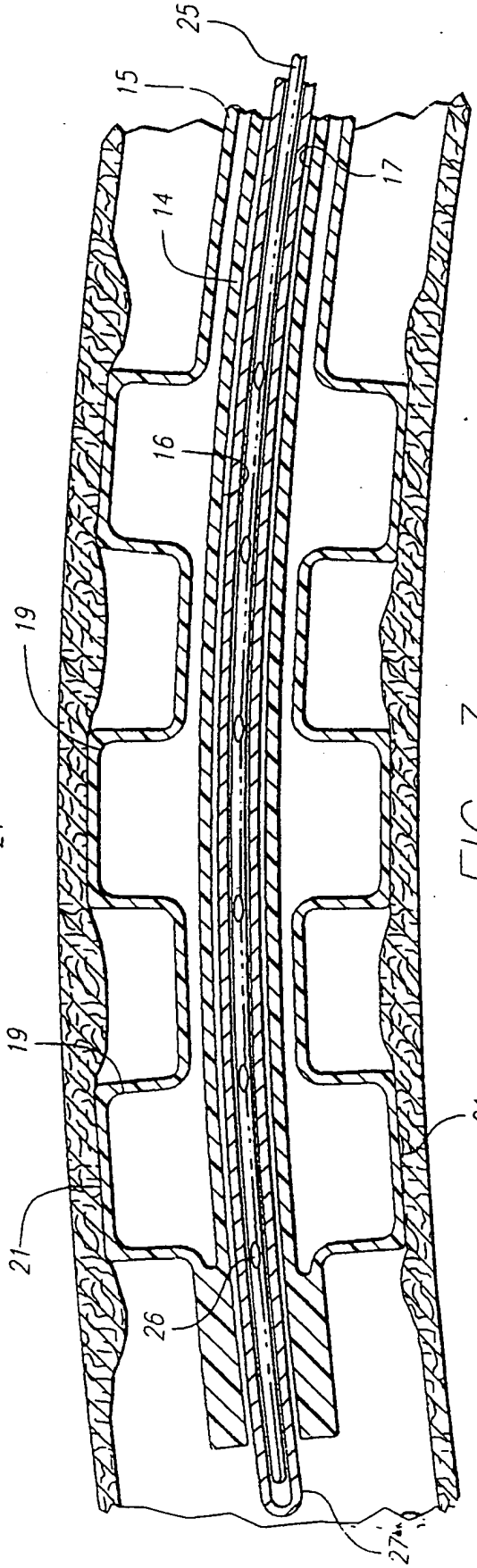
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FIG. 3

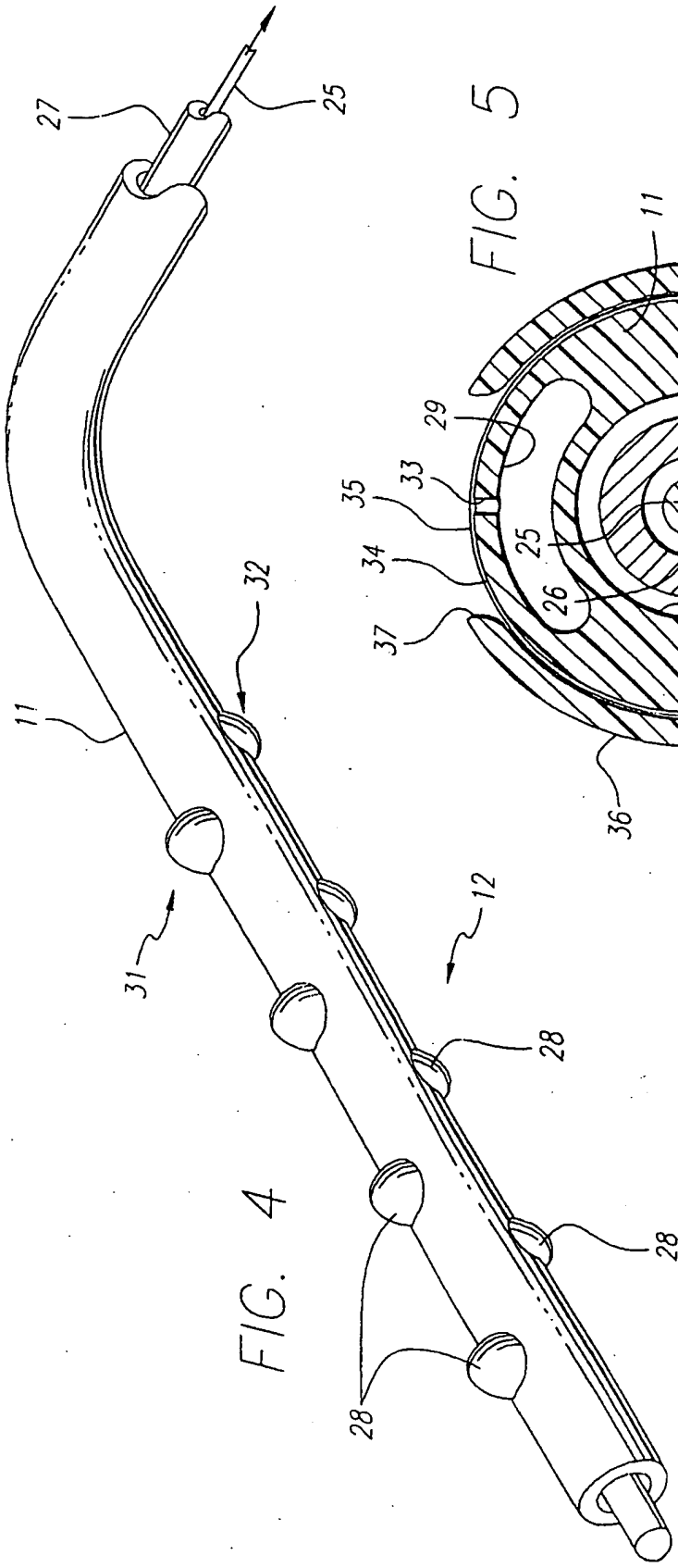

FIG. 4

FIG. 5

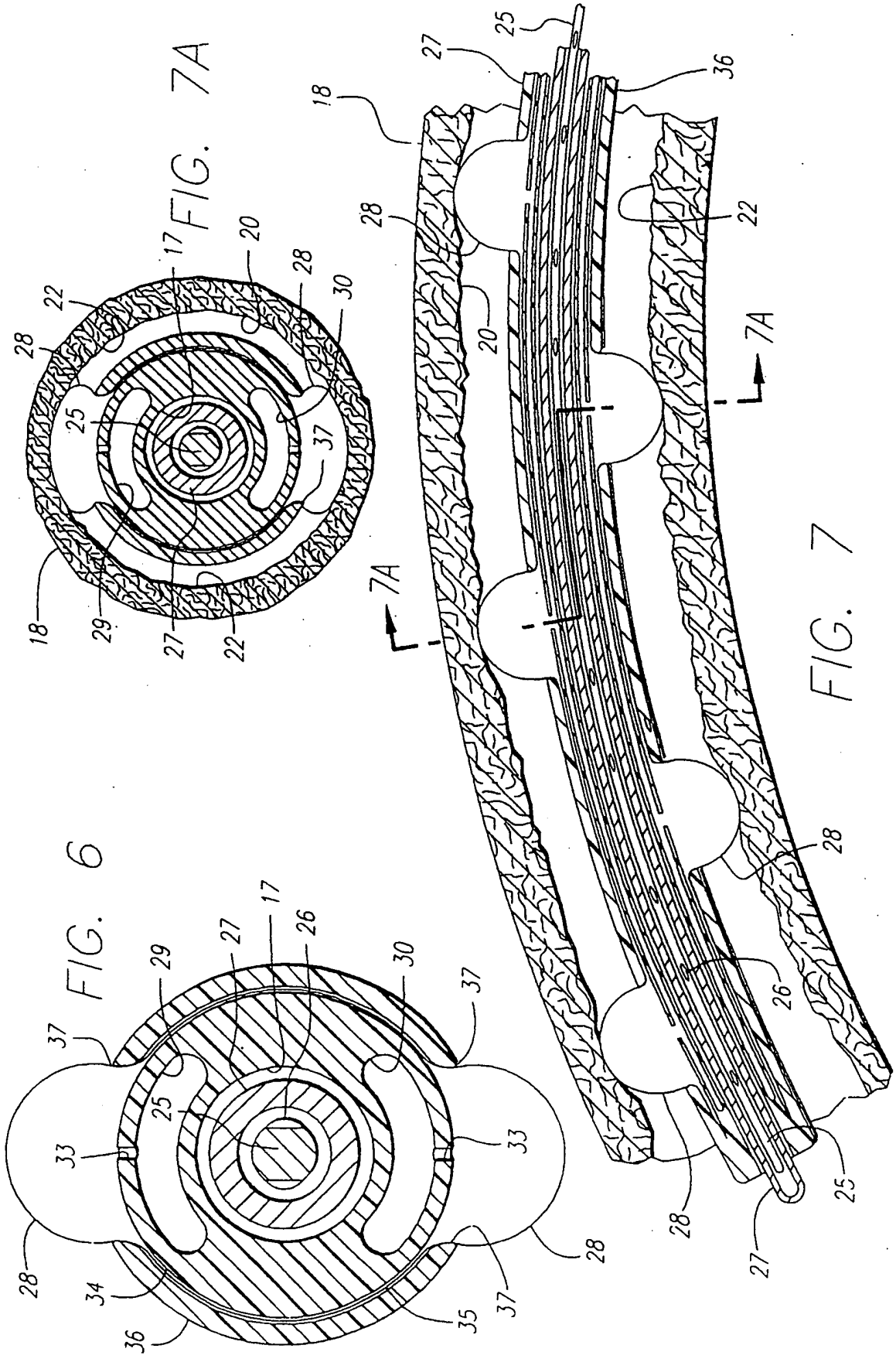
FIG. 7A
FIG. 7
FIG. 6
7A
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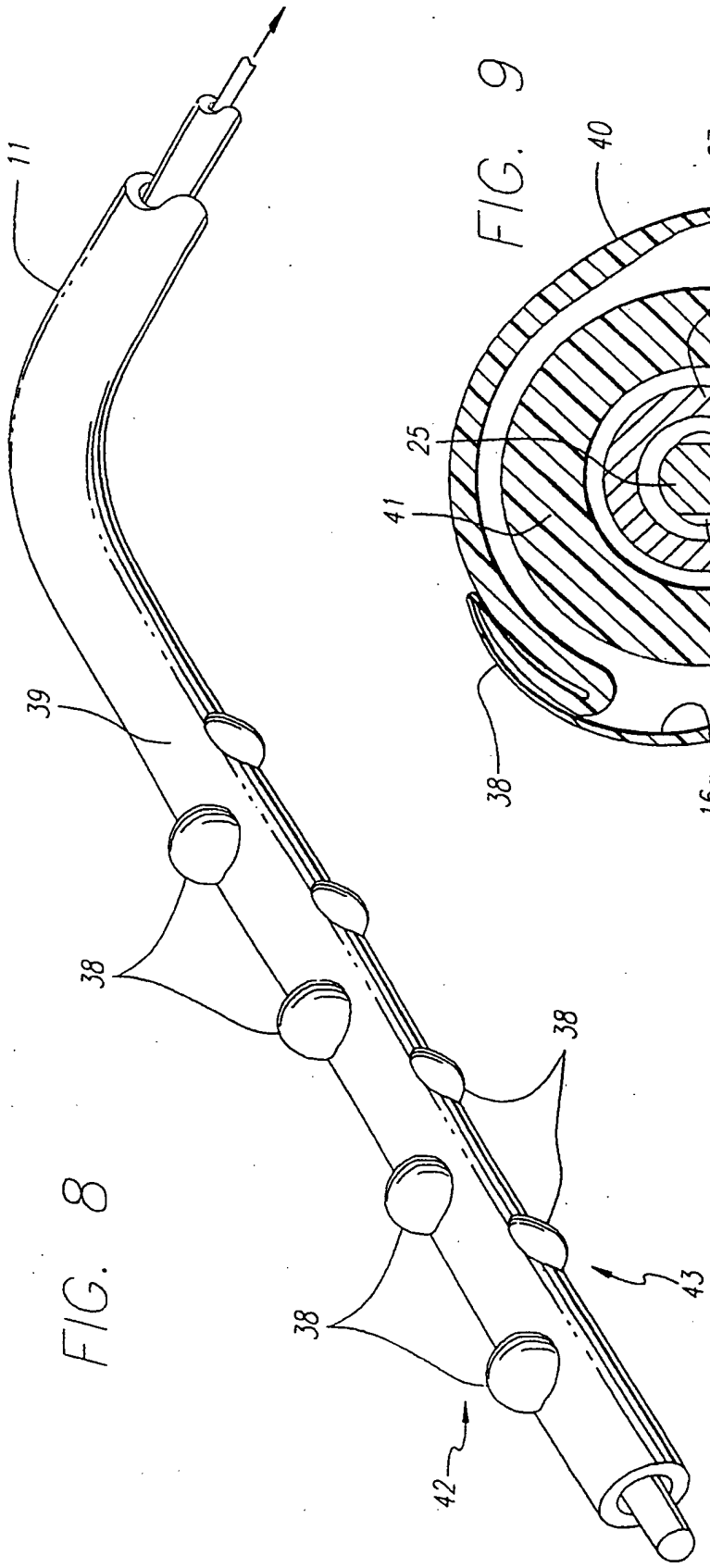

FIG. 8

FIG. 9

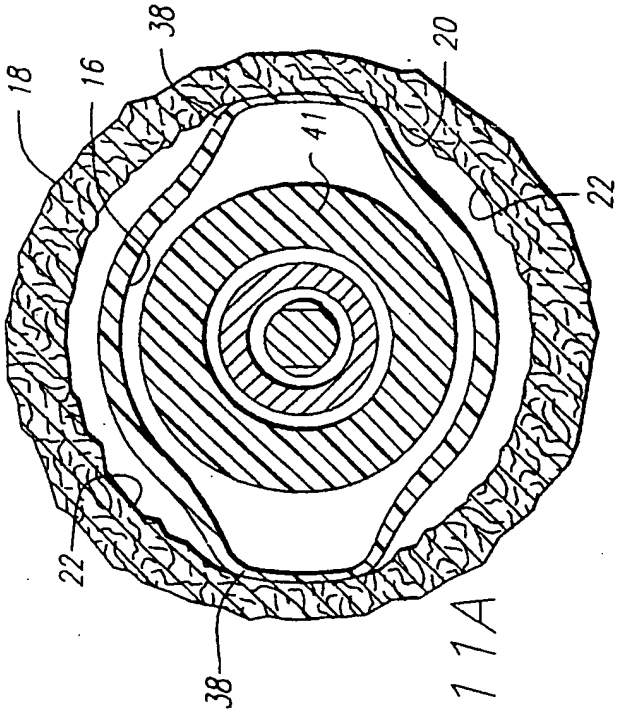

FIG. 11A

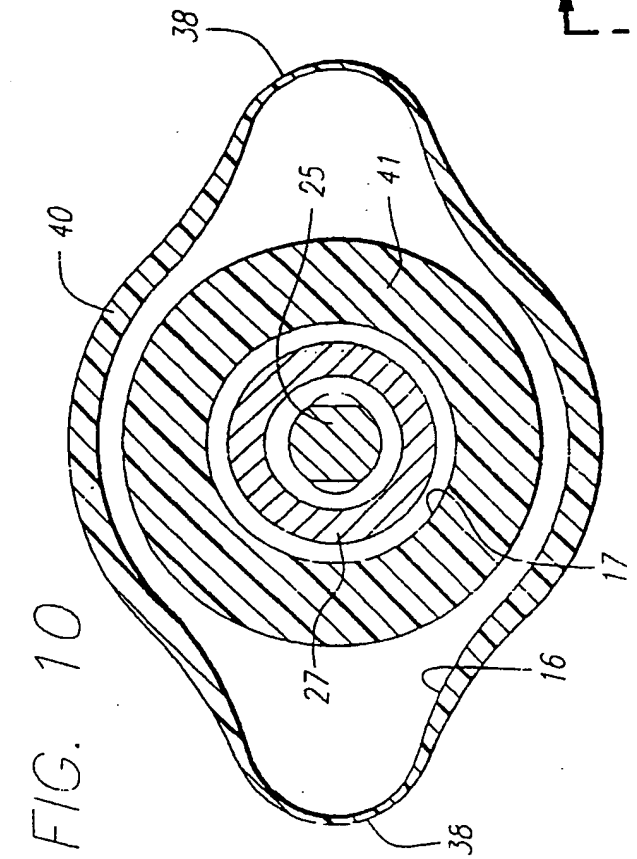

FIG. 10

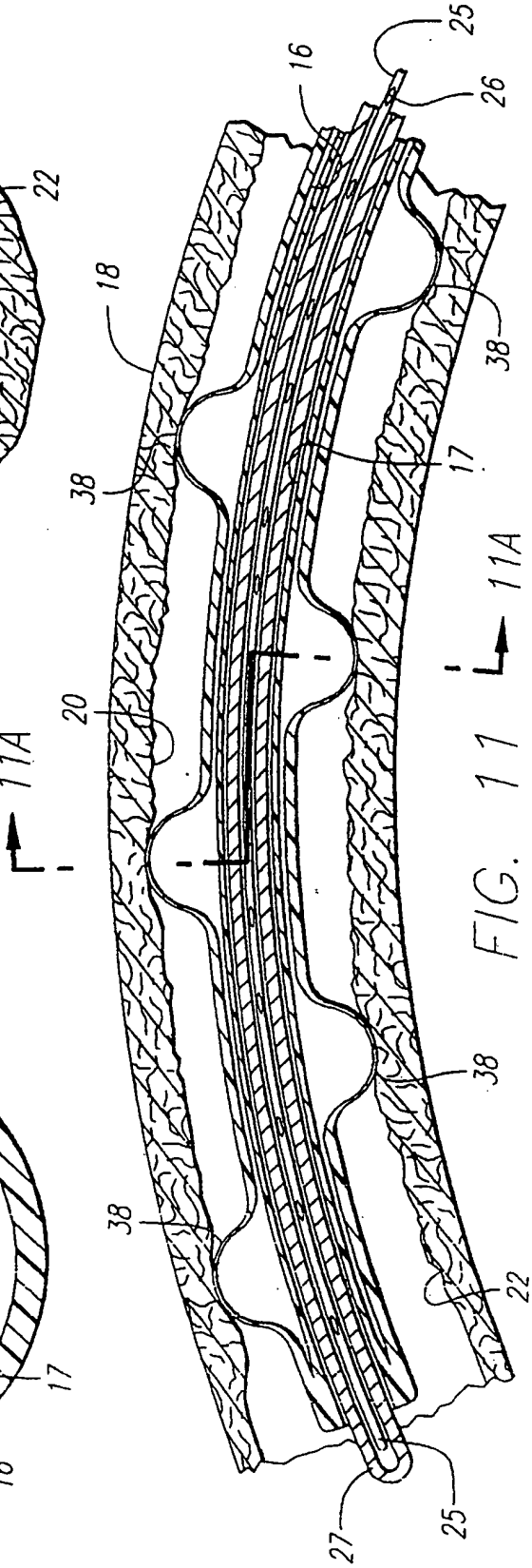

FIG. 11

11A

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N5/10 A61M25/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 98 39052 A (SCIMED LIFE SYSTEMS INC) 11 September 1998 see the whole document ---	1
X	US 5 618 266 A (LIPRIE SAMUEL F) 8 April 1997 see figures 24 and 25 and the related description ---	1,10-14
P,X	EP 0 879 614 A (ADVANCED CARDIOVASCULAR SYSTEM) 25 November 1998 see the whole document ---	1
X	US 5 295 960 A (ALIAHMAD WASSIM ET AL) 22 March 1994 see column 4, line 21 - line 36 see column 6, line 38 - column 7, line 18; figures ---	10,12-14

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 June 1999	18/06/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Clarkson, P

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/03327

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category '	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 395 333 A (BRILL ALAN N) 7 March 1995 see the whole document	10,13,14
X	WO 97 40889 A (APPLE MARC G ;APPLE MELVIN J (US)) 6 November 1997 see figures 7-10	10,12,13
P,X	EP 0 829 271 A (ANGIORAD L L C) 18 March 1998 see figure 12	10,12-14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/03327

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [X] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-9

   An intravascular catheter having a guidewire lumen and an inflatable region, including a protective sheath insertable into the guidewire lumen.

2. Claims: 10-19

   An intravascular catheter having an inflatable region formed by a plurality of nodular balloons.

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